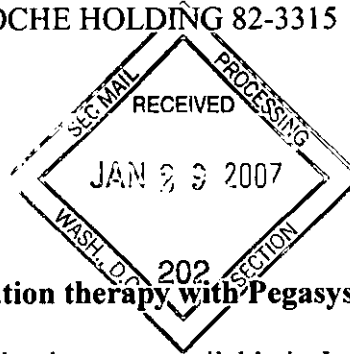


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Basel, 26 January 2007



Copegus approved in Japan as combination therapy with Pegasys for patients with chronic hepatitis C

World's most prescribed hepatitis C combination now available in Japan

Roche and Chugai announced today that the combination of Copegus (ribavirin) plus Pegasys (peginterferon alfa-2a (40KD)) has been approved in Japan following fast track review by the Japanese regulatory agency (MHLW). This is good news for Japanese hepatitis C patients, who now have access to the world's gold standard treatment for the disease.

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The approval in Japan is based on results from a landmark phase III Japanese clinical trial^{1,2} showing that nearly 60% of genotype 1b patients with a high viral load achieved a cure³ with the Pegasys plus Copegus combination treatment. This is a breakthrough as genotype 1 patients are a difficult-to-cure patient group and this result is the highest response rate reported in these patients.

"This approval is another example of our ongoing commitment to give every hepatitis C patient the best chance for a cure" said William M. Burns, CEO of Roche's Pharmaceutical Division, "Together with Chugai, Roche is investigating how we can use current therapies to cure more patients today, while developing new treatment options for the future."

The key results of the study:

- The study was conducted in 300 Japanese hepatitis C patients (200 treatment naïve patients who had genotype 1b and 100 patients who had previously been treated with conventional interferon but did not achieve an SVR). These patients are considered difficult to cure.
- 59.4% of the treatment naïve patients who had genotype 1b and high viral load (≥ 100 KIU/mL) achieved an SVR. This is a significantly higher response rate compared to the group treated with Pegasys alone which was 24%.
- In patients who were pretreated with conventional interferon but did not respond (called 'nonresponders') the response rate in patients who had genotype 1b and high viral load was 51.4% with Pegasys plus Copegus

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No unexpected safety considerations with combination therapy

Overall, the side effect profile was similar in the treatment groups and there was no difference in withdrawal rates. As expected, the rate of anaemia was higher in patients who received ribavirin.

"Approximately 2 million people in Japan are infected with chronic hepatitis C, many of whom are progressing towards severe liver disease at an alarming rate," said Alexander Zehnder, Business Leader for Pegasys at Chugai. "Now with this approval of Copegus, patients and doctors have access to a powerful new ally in

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the fight against this terrible disease.”

About Copegus

Copegus is now approved in Japan and will be marketed by Chugai Pharmaceutical Co Ltd. In Japan, Copegus is approved for use in combination with Pegasys for the treatment of chronic hepatitis C in

1. Patients in serogroup 1 (genotype 1a or 1b with a high HCV-RNA viral load)
2. Non-responders or relapsers to interferon monotherapy

About Pegasys

Pegasys, the market leader worldwide in hepatitis C therapy, provides significant benefit over conventional combination interferon therapy in hepatitis C patients of all genotypes. Pegasys is marketed in Japan by Chugai Pharmaceutical Co. Ltd. In Japan, Pegasys was the first pegylated interferon to be approved and has been reimbursed by the health insurance since December 2003. Pegasys is now also approved in Japan as combination therapy for chronic hepatitis C.

About Hepatitis C in Japan

Hepatitis C is a potentially life threatening viral infection that can lead to liver inflammation, liver disease, cirrhosis or liver cancer. Transmitted through infected blood, approximately 2 million people in Japan are infected with hepatitis C. Worldwide, more than 170 million people are infected making it more prevalent than the HIV virus.

About Genotype

Genotype is the classification of genes of the hepatitis C virus. The most common genotypes in Japanese patients are 1b, 2a, and 2b. In particular, 70% of the total chronic hepatitis C population in Japan are infected with genotype 1b which is considered to be difficult to cure.

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As a supplier of innovative products and services for the early detection, prevention, diagnosis and treatment of disease, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is a world leader in diagnostics, the leading supplier of medicines for cancer and transplantation and a market leader in virology. Roche employs roughly 70,000 people in 150 countries and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai. Additional information about the Roche Group is available on the Internet (www.roche.com).

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Additional information

- [Hepatitis in the Roche Health Kiosk](#)
- About the disease on WHO's homepage
- Film footage is available for broadcast journalists from The NewsMarket at www.thenewsmarket.com. Video is compressed in MPEG2 and is available for download to your FTP server.

References:

- 1) Sakai T, Iino S, Okuno T et al. High response rates with peginterferon alfa-2a (40KD) (PEGASYYS®) plus ribavirin (COPEGUS®) in treatment-naïve Japanese chronic hepatitis C patients: a randomised, double-blind, multicentre, phase III trial. J Hepatol 2006;44 (Suppl 2): S224
- 2) Izumi N, Iino S, Okuno T et al. High response rates with peginterferon alfa-2a (40KD) (PEGASYYS®) plus ribavirin (COPEGUS®) in Japanese non-responders or relapsers to conventional interferon. J Hepatol 2006;44 (Suppl 2): S216
- 3) Sustained virological response (SVR)

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